K071301

510(k) Summary

MAY 24 2007

ANTLIA I™ WOUND IRRIGATION SYSTEM

1. **Name/Address of Submitter:** **Innovative Therapies, Inc.**
   10948 Beaver Dam Road, Suite C
   Hunt Valley, MD 21030

2. **Contact Person:** **Judith Harbour**
   Phone: 866-200-0412
   e-mail: jharbour@charter.com

3. **Date Summary Prepared:** **May 4, 2007**

4. **Name of Device:** **ANTLIA I™ Wound Irrigation System**

5. **Classification Name:** **Powered Suction Pump**
   21 CFR 878.4780
   Class II

6. **Predicate Device:** **V.A.C.® Instill™**
   510(k) No.K021501

7. **Description of Device**

   The ANTLIA I™ Wound Irrigation System is an AC-powered, portable suction device with battery back-up that provides vacuum assisted drainage and irrigation of a wound site by controlled delivery of topical wound treatment solutions over the wound bed.

   The specifically designed Aquarius I™ dressing components are provided for irrigation to a wound with sterile saline or other applicable topical solutions. During and after irrigation, negative pressure can be applied to assist in the removal of infectious materials or other fluids.

8. **Indication For Use**

   The ANTLIA I™ Wound Irrigation System device is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

   The ANTLIA I™ Wound Irrigation System is intended for patients with chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

9. Technological Characteristics and Substantial Equivalence

The ANTLIA I™ Wound Irrigation Therapy Unit has essentially the same technological characteristics as the previously cleared predicate device and has been independently tested and successfully approved to the following medical safety standards:

- IEC 60601-1 + US deviations (UL60601-1), Medical Electrical Equipment– Part1:General Requirements for Safety; 1. Collateral Standard: Safety Requirements for Medical electrical Systems
- EN 60601-1-2: 2001 version (2nd Edition), Medical Electrical Equipment – Part 1-2: General Requirements for Safety–2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC 60601-1-4, Medical Electrical Equipment – Part 1: General Requirements for Safety -4.Collateral Standard: Programmable Electrical Medical Systems

10. Conclusion

The substantial equivalence for the ANTLIA I™ Wound Irrigation System is based on the same indications, intended use, and technological features of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 14 2010

Innovative Therapies, Inc.
% Ms. Judith Harbour
12 Meens Avenue, Suite C
Gaithersburg, Maryland 20877

Re: K071301
Trade/Device Name: ANTLIA I™ Wound Irrigation System
Regulation Number: 21 CFR 878.4780
Regulation Name: Negative Pressure Wound Therapy Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 8, 2007
Received: May 9, 2007

Dear Ms. Harbour:

This letter corrects our substantially equivalent letter of May 24, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071301

Device Name: ANTLIA 1™ Wound Irrigation System

Indications For Use:

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The ANTLIA 1™ Wound Irrigation System is intended for patients with chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use ___v___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Gen... ...
and Neurological ...

510(k) Number K071301